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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/873,751	06/04/2001	Kenneth M. Phillips	6807.US.O1	4856

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ROSS PRODUCTS DIVISION OF ABBOTT LABORATORIES
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EXAMINER	
MCINTOSH III, TRAVISS C	
ART UNIT	**PAPER NUMBER**
1623	8

DATE MAILED: 12/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

File Copy

Office Action Summary	Application No.	Applicant(s)	
	09/873,751	PHILLIPS ET AL.	
	Examiner	Art Unit	
	Traviss C McIntosh	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 September 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The Examiner of the U.S. Patent application SN 09/873,751 has changed. In order to expedite the correlation of papers with the application please direct all future correspondence to the Technology Center 1600, Art Unit 1623, attn: Examiner Traviss McIntosh.

The Amendment filed September 11, 2003 has been received, entered into the record, and carefully considered. The following information provided in the amendment affects the instant application by:

Claims 4, 7-8, 12-13, 17, and 19 have been amended.

Claims 21-22 have been canceled.

The amendments to the specification have not been entered.

Remarks drawn to rejections of Office Action mailed March 11, 2003 include:

103(a) rejection: which has been maintained for reasons of record.

An action on the merits of claims 1-20 is contained herein below.

The text of those sections of Title 35, US Code which are not included in this action can be found in a prior Office action.

Response to Amendment

The amendment to the specification filed on September 11, 2003 does not comply with the requirements of 37 CFR 1.121. Amendments filed on or after July 30, 2003 must comply with 37 CFR 1.121 which states:

37 CFR 1.121. Manner of making amendments in application.

(A) Amendments in applications, other than reissue applications . Amendments in applications, other than reissue applications, are made by filing a paper, in compliance with § 1.52, directing that specified amendments be made.

(B) Specification other than the claims and listings provided for elsewhere (§ § 1.96 and 1.825) .

(1) Amendment by instruction to delete, replace, or add a paragraph. Amendments to the specification, other than the claims and listings provided for elsewhere (§ § 1.96 and 1.825), may be made by submitting:

(i) An instruction, which unambiguously identifies the location, to delete one or more paragraphs of the specification, replace a deleted paragraph with one or more replacement paragraphs, or add one or more paragraphs;

(ii) Any replacement or added paragraph(s) in clean form, that is, without markings to indicate the changes that have been made; and

(iii) Another version of any replacement paragraph(s), on one or more pages separate from the amendment, marked up to show all the changes relative to the previous version of the paragraph(s). The changes may be shown by brackets (for deleted matter) or underlining (for added matter), or by any equivalent marking system. A marked up version does not have to be supplied for an added paragraph or a deleted paragraph as it is sufficient to state that a particular paragraph has been added, or deleted.

(2) Amendment by replacement section . If the sections of the specification contain section headings as provided in § § 1.77(b), 1.154(b), or § 1.163(c), amendments to the specification, other than the claims, may be made by submitting:

(i) A reference to the section heading along with an instruction to delete that section of the specification and to replace such deleted section with a replacement section;

(ii) A replacement section in clean form, that is, without markings to indicate the changes that have been made; and

(iii) Another version of the replacement section, on one or more pages separate from the amendment, marked up to show all changes relative to the previous version of the section. The changes may be shown by brackets (for deleted matter) or underlining (for added matter), or by any equivalent marking system.

(3) Amendment by substitute specification . The specification, other than the claims, may also be amended by submitting:

(i) An instruction to replace the specification;

(ii) A substitute specification in compliance with § 1.125(b); and

(iii) Another version of the substitute specification, separate from the substitute specification, marked up to show all changes relative to the previous version of the specification.

The changes may be shown by brackets (for deleted matter), or underlining (for added matter), or by any equivalent marking system.

Claim Rejections - 35 USC § 103

The rejection of claims 1-15 as being unpatentable under 35 U.S.C. 103(a) as being over Waite et al. (US Patent 5,869,459) in view of Johns Hopkins Press Release (*Zinc supplements important in combating diarrhea – 12/27/00*) is maintained for reasons of record.

Claims 1-15 are drawn to methods of providing oral rehydration therapy comprising administering an aqueous solution comprising sodium, potassium, zinc, citrate and a carbohydrate in various amounts.

Waite et al. teach a method of providing a rehydration formulation for the replacement of electrolytes and enhanced water retention. The composition of Waite et al. comprises sodium, potassium, citrate and carbohydrates in the same ranges as in the instant. What is not specifically taught is to add zinc to the composition. However, on column 7, lines 5-12, Waite et al. indeed contemplate adding zinc, in the form of zinc chloride, to the composition.

The Johns Hopkins press release teaches that when zinc is administered in conjunction with oral rehydration therapy during recovery from acute or persistent diarrhea, the zinc supplements helped the children suffering from acute and persistent diarrhea to significantly reduce the duration of their symptoms.

The active agents and designated concentrations set forth in the prior art overlap substantially with the active agents and concentrations instantly claimed. Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to combine the art recognized oral rehydration agents of sodium, potassium, zinc, citrate, chloride, carbohydrates, and water to form an oral rehydration solution and administer the solution to the patient in need thereof. It requires nothing more than routine skill in the art to combine art recognized active

agents to form an oral rehydration solution and administer the combined composition to treat dehydration and related symptoms and conditions since the art teaches that these agents are shown in the art to treat dehydration either individually or when used in combination. One would have been motivated to add zinc to the Waite composition, because Waite et al. contemplate the use of zinc, in such forms as zinc chloride, and John Hopkins teaches the importance of zinc for remedying dehydration.

Applicant's arguments filed September 11, 2003 have been fully considered but they are not persuasive. Applicants argue that the Hopkins press release administered zinc in a separate tablet rather than in the oral rehydration solution, and that both Waite and the Hopkins press release teach of the disagreeable tastes of electrolytes. However, the Johns Hopkins reference is cited to show that the combination of oral rehydration solutions and zinc has greater efficacy than the oral rehydration solution alone, thus one of skill in the art would indeed find it obvious to add zinc to the previously art known oral rehydration solutions to enhance the efficacy of the solution. The references are cited to show what they teach as a whole. The Johns Hopkins article teaches to administer zinc to enhance the efficacy of the oral rehydration solutions, and Waite et al. contemplate adding zinc to their solution. One would find it obvious to add zinc to an oral rehydration solution and would be motivated to add zinc to the solution to enhance the efficacy of the oral rehydration solution with these references before them.

The rejection of claims 16-20 as being unpatentable under 35 U.S.C. 103(a) as being over Waite et al. (US Patent 5,869,459) in view of Johns Hopkins Press Release (*Zinc supplements important in combating diarrhea – 12/27/00*) and Ndife et al. (US Patent 5,489,440) is maintained for reasons of record.

Claims 16-20 are drawn to compositions comprising sodium, potassium, zinc, citrate, carbohydrate, and water, and optionally a gelling agent, rice flower, or an indigestible oligosaccharide.

Waite et al. and the Johns Hopkins press release teach of oral rehydration solutions as set forth supra (and in the previous office action), what is not taught is to add rice flower.

Ndife et al. teach to add rice flower to oral rehydration solutions (see claims 1-14) wherein oral rehydration solutions prepared from rice may not only ameliorate dehydration, but may also decrease diarrheal fluid loss and reduce stool output.

It would have been obvious to one of ordinary skill in the art at the time of the invention to add rice flour to an oral rehydration solution, as Ndife et al. teaches that the addition of rice flour indeed increases the efficacy of the rehydration solution. It requires nothing more that routine skill in the art to combine art recognized active agents to form a oral rehydration solution and administer the combined composition to treat dehydration and related symptoms and conditions since the art discloses these agents are shown to treat dehydration either individually or when in combination.

Applicant's arguments filed September 11, 2003 have been fully considered but they are not persuasive. Applicants argue that the Hopkins press release administered zinc in a separate tablet rather than in the oral rehydration solution, and that both Waite and the Hopkins press release teach of the disagreeable tastes of electrolytes. However, the Johns Hopkins reference is cited to show that the combination of oral rehydration solutions and zinc has greater efficacy than the oral rehydration solution alone, thus one of skill in the art would indeed find it obvious to add zinc to the previously art known oral rehydration solutions to enhance the efficacy of the

solution. The references are cited to show what they teach as a whole. The Johns Hopkins article teaches to administer zinc to enhance the efficacy of the oral rehydration solutions, Ndife et al teach to add rice flour to decrease diarrheal fluid loss and reduce stool output, and Waite et al. contemplate adding zinc to their solution. One would find it obvious to add zinc to an oral rehydration solution and would be motivated to add zinc to the solution to enhance the efficacy of the oral rehydration solution with these references before them.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Traviss C McIntosh whose telephone number is 703-308-9479. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 703-308-4624. The fax phone number for the organization where this application or proceeding is assigned is 703-305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

James O. Wilson
Supervisory Patent Examiner
Art Unit 1623

Traviss C. McIntosh III
December 1, 2003